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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/668,119	09/22/2000	William B. Solomon	011.00250	9568

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EXAMINER

LOEB, BRONWEN

ART UNIT	PAPER NUMBER
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163C

DATE MAILED 05/09/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/668,119

Applicant(s)

SOLOMON ET AL.

Examiner

Bronwen M. Loeb

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 18-22 and 25-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17, 23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: "Copy of Papers Originally Filed" info.

09/668, 119

The following papers have not been made part of the permanent records of the United States Patent and Trademark Office (Office) for this application (37 CFR 1.52(a)) because of damage from the United States Postal Service irradiation process:

Mailroom Stamp Date

Certificate of Mailing Date

13 FEB 2002

23 JAN. 2002

The above-identified papers, however, were not so damaged as to preclude the USPTO from making a legible copy of such papers. Therefore, the Office has made a copy of these papers, substituted them for the originals in the file, and stamped that copy:

**COPY OF PAPERS
ORIGINALLY FILED**

If applicant wants to review the accuracy of the Office's copy of such papers, applicant may either inspect the application (37 CFR 1.14(d)) or may request a copy of the Office's records of such papers (*i.e.*, a copy of the copy made by the Office) from the Office of Public Records for the fee specified in 37 CFR 1.19(b)(4). Please do **not** call the Technology Center's Customer Service Center to inquiry about the completeness or accuracy of Office's copy of the above-identified papers, as the Technology Center's Customer Service Center will **not** be able to provide this service.

If applicant does not consider the Office's copy of such papers to be accurate, applicant must provide a copy of the above-identified papers (except for any U.S. or foreign patent documents submitted with the above-identified papers) with a statement that such copy is a complete and accurate copy of the originally submitted documents. If applicant provides such a copy of the above-identified papers and statement within **THREE MONTHS** of the mail date of this Office action, the Office will add the original mailroom date and use the copy provided by applicant as the permanent Office record of the above-identified papers in place of the copy made by the Office. Otherwise, the Office's copy will be used as the permanent Office record of the above-identified papers (*i.e.*, the Office will use the copy of the above-identified papers made by the Office for examination and all other purposes). This three-month period is not extendable.

DETAILED ACTION

This action is in response to the communication filed 13 February 2002
(Certificate of Mailing date 23 January 2002).

Claims 1-36 are pending.

Election/Restrictions

1. Applicant's election with traverse of Group I in Paper No. 11 is acknowledged. The traversal is on the ground(s) that the search of the inventions of Group I and II together would not place a serious burden on the Examiner. This is not found persuasive because Group I comprises a first method of use of the nucleic acid product (SEQ ID No. 1), which is a method of inhibiting expression of SEQ ID No. 1 by means of antisense nucleic acid. Group II is drawn to a method of expressing the product of SEQ ID No. 1. These methods are very different and require different searches.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 18-22 and 25-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

Drawings

3. The drawings are objected to because Figure 4 is illegible. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid

abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

4. The abstract of the disclosure is objected to because it exceeds 150 words.

Correction is required. See MPEP § 608.01(b).

5. The disclosure is objected to because of the following informalities: The word "Introduction" found in the middle of the spec (p. 28) and after the EXAMPLE; the introduction part of specification, titled "Background of the Invention", usually is found at the start of the specification, after the Field of the Invention and prior to Brief Description of the Drawings.

Appropriate correction is required.

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Nucleic acid that encodes a transcriptional adaptor protein.

Claim Objections

7. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 2 does not seem to

further limit claim 1 because there is no ambiguity in SEQ ID No. 1 therefore it must encode the amino acid sequence of SEQ ID NO. 3.

Claim Rejections - 35 USC § 101 and 35 USC § 112

8. 35 U.S.C. §101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-17, 23 and 24 are rejected under 35 U.S.C. §101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well-established utility.

Claim 1 is drawn to an isolated nucleic acid having a nucleotide sequence of SEQ ID No. 1, which encodes a protein called TIG-1. Claim 23 is drawn to an isolated nucleic acid encoding an amino acid sequence having as least 90% amino acid identity with SEQ ID No. 3. The specification discloses that SEQ ID No. 1 was cloned from an EST library enriched in cDNAs from TPA-induced K562 human leukemia cells (p. 30). Based on the deduced amino acid sequence, the protein appears to have a putative protein kinase C phosphorylation site (p. 43, lines 12-14), a putative bipartite nuclear localization signal and seven glutamine-rich repeat regions but no DNA binding region (p. 39, lines 7-22). It is "hypothesized that the TIG-1 protein may function as a transcriptional coactivator factor" (p. 43, lines 19-22. It is further speculated that TIG-1

is involved in chromatin structure remodeling related to megakaryocytic differentiation (p. 45) and that it may be related to ARC and DRIP (p. 44, lines 3-28). A chimeric protein comprising TIG-1 and the Gal4 DNA binding domain shows some modest transcription activation using a reporter gene construct. The uses taught for the nucleic acid are generic to any protein-encoding nucleic acid: probes, assays for things that bind the protein and production of antibodies against the protein to use in screening for expression of the protein (pp.19-27). There is no well-established, specific and substantial utility for the claimed nucleic acid as the skilled artisan would have to determine the actual function of the polypeptide or polypeptide fragment encoded by the nucleic acid in order to determine how to use it. The skilled artisan would need to prepare, isolate and analyze the polypeptide or polypeptide fragment encoded by the nucleic acid in order to determine its specific function and use. Therefore the invention is not in a readily available form. Instead, further experimentation on the polypeptide or polypeptide fragment encoded by the nucleic acid would be required before it could be used.

10. Claims 1-17, 23 and 24 are also rejected under 35 U.S.C. §112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that

form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. Claims 8, 9 and 24 are rejected under 35 U.S.C. §102(b) as being anticipated by Margolis et al (Hum Gen (1997) 100:114-122) and accession number HSU80745 (Database GenEMBL, accessed 1 March 2002. 18 December 1997. Accession number HSU 80745).

Margolis et al teach an oligonucleotide complementary to at least a portion of the mRNA obtained from SEQ ID No. 1. A cell comprising the oligonucleotide is taught. See entire document, particularly clone CTG7a in Tables 1 and 2.

13. Claims 8, 9 and 24 are rejected under 35 U.S.C. §102(b) as being anticipated by Philibert et al (European Journal of Human Genetics (1998) 6:89-94) and accession number AF021108 (Database GenEMBL, accessed 1 May 2002. 3 April 1998. Accession number AF021108).

Philibert et al teaches an oligonucleotide complementary to at least a portion of the mRNA obtained from SEQ ID No. 1. A cell comprising the oligonucleotide is taught. See entire document, particularly cosmid 13 in Table 1, corresponding to Genbank accession number AF021108.

14. Claims 8-10 and 24 are rejected under 35 U.S.C. §102(b) as being anticipated by Hillier et al (Database EST accessed 1 March 2002. 12 November 1997. Accession number AA664125).

Hillier et al teaches an oligonucleotide complementary to at least a portion of the mRNA obtained from SEQ ID No. 1. A cell comprising the oligonucleotide is inherent to Hillier et al as the library was in SOLR host cells. The oligonucleotide is in the expression vector pBluescript SK-. See entire document.

15. Claims 8, 9 and 24 are rejected under 35 U.S.C. §102(b) as being anticipated by Orr et al (UPS 5,741,645).

Orr et al teaches an oligonucleotide complementary to at least a portion of the mRNA obtained from SEQ ID No. 1. A cell comprising the oligonucleotide is taught. See entire document, particularly SEQ ID No. 3 in Figure 2.

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Conclusion

Claims 1-17, 23 and 24 are rejected. Claims 1-7, 11-17 and 23 are free of prior art.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bronwen M. Loeb whose telephone number is (703) 605-1197. The examiner can normally be reached on Monday through Friday, from 10:00 AM to 6:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than the next business day after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Remy Yucel, can be reached on (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application should be directed to Tracey Johnson, Patent Analyst whose telephone number is (703) 305-2982.

Bronwen M. Loeb, Ph.D.
Patent Examiner
Art Unit 1636

May 6, 2002

DAVID GUZO
PRIMARY EXAMINER
